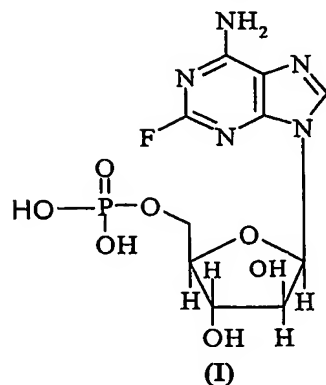


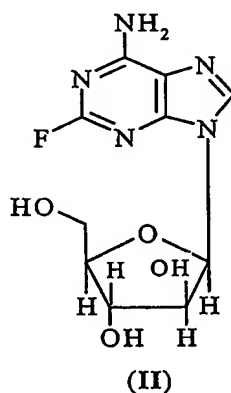
CLAIMS

1. A process for the preparation of fludarabine phosphate (I)

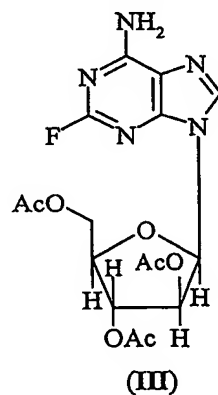


- 5 comprising the following steps:

- a) reaction of 2-fluoroadenine with 9-β-D-arabinofuranosyl-uracil in the presence of *Enterobacter aerogenes* to give crude fludarabine (II);



- 10 b) treatment of crude fludarabine with acetic anhydride to give 2',3',5'-tri-O-acetyl-9-β-D-arabinofuranosyl-2-fluoroadenine (III);



c) hydrolysis and recrystallisation of compound (III) to give pure fludarabine (II);

d) phosphorylation of fludarabine to give fludarabine phosphate (I).

2. A process according to claim 1 wherein step a) is carried out at a temperature comprised between 50 and 70°C, and the molar ratio between 9-β-D-arabinofuranosyl-uracil and 2-fluoroadenine ranges from 5:1 to 7:1.

3. A process according to claim 1 or 2 wherein crude fludarabine from step a) is recovered by dialysis.

4. A process according to anyone of claims 1 - 3 wherein step b) is carried out by dissolving crude fludarabine in 9 - 11 volumes of acetic anhydride at 90 - 100°C.

5. A process according to any one of claims 1 - 4 wherein intermediate (III) from step b) is hydrolysed with methanol and ammonium hydroxide.

6. A process according to any one of claims 1 - 5 wherein fludarabine obtained from step c) is hot-crystallised from water or from a water/ethanol mixture.

7. A process according to any one of claims 1 - 6 wherein the phosphorylation reaction of step d) is carried out at -10°C and the resulting fludarabine phosphate is precipitated from water at 0°C.

8. A process according to any one of claims 1 - 7 wherein fludarabine phosphate is purified by treatment with an organic amine or NH₄OH followed by acidic hydrolysis.

9. A process according to claim 8 wherein the organic amine is selected from the group consisting of triethylamine, diisopropylamine, benzylamine, tributylamine, dibenzylamine and dicyclohexylamine.

10. Fludarabine phosphate salts with organic amines or with ammonia.